

Remark

This Amendment is in response to the Office Action dated **December 13, 2007**.

Applicant has canceled claim 30-32 as they have not been acted on. These claims were added in the Amendment dated April 19, 2002 but were not acted on in the previous Office Action mailed 1/15/03.

Rejections

35 U.S.C. 103(a)

Claims 1, 3-8 and 23-29 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Booth et al., U.S. Patent No. 5,653,690 in view of Elton, U.S. Patent No. 5,077,352 and further in view of Abele et al., U.S. Patent No. 6,010,480. It is asserted in the Office Action that:

In figure 4, Booth et al. shows a medical device insertable in the body "wherein the balloon 74 incorporates a hydrophilic coating 130 on its outer surface....The Elton patent demonstrates that the use of thermoplastic and thermosetting coatings in catheters is conventional in the art. Accordingly, for a person of ordinary skill in the art, modifying the balloon catheter disclosed y Booth et al. with the coatings disclosed by Elton would have been considered obvious in view of the conventionally of said coatings.

In relation to the claim limitation disclosing a "substantially uniform noncontinuous protective surface coating", Abele et al. shows in figures 7 and 8, coatings applied in waffle and stripe patterns.

Office Action, pages 3 and 4.

With this rejection, Applicant disagrees.

However, for purposes of clarification only, claim 1 has been amended to recite that the balloon is formed from a first layer that is exposed where the surface coating is

discontinuous. Support for this can be found at least from page 3, lines 15-20 wherein it is clear that the balloon underlayer is exposed.

Independent claim 3 has also been amended in accordance with claim 1 and is not directed to a dilatation balloon having improved durability formed from a thermoplastic polymer, said balloon having a non-continuous protective coating, the balloon formed from a first polymer layer, wherein the first polymer layer is exposed where the protective coating is non-continuous.

Independent claim 23 has also been amended in accordance with claim 1 and is not directed to 1 medical device insertable in the body having a protective coating on a surface thereof, the coating being applied to said medical device in a substantially uniform discontinuous pattern, the medical device formed from a first polymer layer, the first polymer layer is exposed by the substantially uniform discontinuous pattern of the protective coating.

The amendment to claims 3 and 23 is also supported at least from page 33, lines 15-20. See also page 2, lines 27-31 and page 3, lines 1-5. No new matter has been added.

Independent claim 27 has been amended to depend from claim 3. Claim 27 was substantially similar to claim 3 except for the recitation that the balloon was formed from a thermoplastic polymer. No new matter has been added.

Applicant submits that Booth et al. is directed to a catheter for retrograde perfusion having a balloon with retention enhancement. See Abstract. A hydrophilic coating can be incorporated on the balloon outer surface for adhering to the interior surface of the coronary sinus. See Fig. 24 and the description therefore. There is no disclosure as to the coating being discontinuous in nature.

Elton discloses flexible lubricious coatings. See Abstract. There is no disclosure that the coating be discontinuous on a surface.

Abele et al. disclose “[a]n expansible balloon catheter has at least a first exterior surface with a given coefficient of friction and a second exterior surface with a greater coefficient of friction.” Abstract. Abele et al., with respect to Fig. 8, disclose:

FIG. 8 depicts another embodiment in which the surface 32 is treated with an array of molded pockets 35 bounded by circumferentially and longitudinally extending ribs 36 and 37. When expanded this waffle-like surface gently contacts adjacent tissue and anchors the balloon 15 in place. In either of the embodiments of FIGS. 7 or 8, the material forming the surfaces 32 and 27 may be the same. The ribs 34 in FIG. 7 and the ribs 36 and 37 in FIG. 8 would be coextensive only with the surface 32. In accordance with one manufacturing process, a slippery coating, such as a hydrogel material, would be applied to the entire surface of the balloon. Then a material etching process, such as laser etching, would form the ribs 34 or ribs 36 and 37 by removing the intermediate portions of the coating.

Column 6, lines 51-64.

However, in looking at Fig. 8 it is very clear that surface 32 is continuous, even though there are ribs formed in it because the underlying honeycomb core is not exposed.

Consequently, this combination of references fails to disclose or suggest a characterizing feature of claim 1, namely, the discontinuous surface coating which exposes the balloon underlayer.

Furthermore, Applicant’s discontinuous coating is for the purpose of preventing the formation of a bulge in an outer coating layer when a pinhole forms in the balloon underlayer.

Efforts have been made to coat a balloon with a continuous coating of a thin durable material. The problem associated with such continuous coatings is that if a pinhole is present in the underlying balloon material, as the balloon is inflated, the coating will also inflate, and at the point of the pinhole, can separate from the balloon material and form a bubble which can dissect an artery or vessel.

Specific examples of such problems occur with oriented PET which is commonly used for forming catheter balloons by a stretch blow molding method. The PET can exhibit pinholes that emit a high-velocity jet of inflation fluid during inflation. This then will result in the bulge forming in the outer coating layer which can cause artery dissection. Pet also exhibits low tear resistance and does not take a crease.

Specification, page 2, lines 27-31 and page 3, lines 1-5.

There is no recognition by Booth et al., Elton or Abele et al. of such a problem, and consequently, there is no solution to the problem that can be found in any of these references via application of a discontinuous coating layer which can protect from abrasion and scratches, while not bulging in the event of pinhole formation in the balloon underlayer.

MPEP 2142 describes how a *prima facie* determination of obviousness is made:

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. MPEP 2142

Recognition of a problem, and the solution to the problem, is recognized as being part of the analysis of the "invention as a whole".

"[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Spinnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969). However, "discovery of the cause of a problem . . . does not always result in a patentable invention. . . . [A] different situation exists where the solution is obvious from prior art which contains the same solution for a similar problem." *In re Wiseman*, 596 F.2d 1019, 1022, 201 USPQ 658, 661 (CCPA 1979) (emphasis in original). MPEP 2141.02.

This combination of references fails to render claim 1 obvious because the combination neither discloses nor suggests a balloon having a discontinuous coating wherein the

balloon underlayer is exposed as recited in claim 1, for the purpose of preventing bulges in the outer coating in the event of pinhole formation.

Claim 3 has also been amended to recite that the balloon is formed from a first polymer layer that is exposed by the discontinuous coating and is also not obvious over this combination for at least the reasons that claim 1 is not obvious over this combination.

Claims 4-8 and 27-29 depend from claim 3 and are not obvious over this combination for at least the reasons that claims 1 and 3 are not obvious over this combination.

Independent claim 23 has also been amended accordingly and is also not obvious over this combination at least for the reasons that claims 1 and 3 are not obvious over this combination as discussed above.

CONCLUSION

Claims 1, 3-8 and 23-29 are pending in this application. Applicant has addressed each of the issues presented in the Office Action. Based on the foregoing, Applicant respectfully requests reconsideration and an early allowance of the claims as presented. Based on the fact that this application was filed on January 4, 2000, and that it has been nearly five years between office actions, Applicant respectfully requests expeditious examination of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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